UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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NORMA JEAN PARTIE, Plaintiff(s), v. ETHICON, INC., et al., Defendant(s).	Case No. 2:21-CV-1366 JCM (BNW) ORDER

Presently before the court is defendants Johnson & Johnson ("J&J") and Ethicon, Inc.'s ("Ethicon") (collectively "defendants") motion to dismiss. (ECF No. 9). Plaintiff Norma Jean Partie ("Partie") filed a response (ECF No. 11), to which defendants replied (ECF No. 12).

I. Background

This action arises from the surgical implant of defendants' pelvic mesh product known as the Gynecare TVT Abbrevo Continence System ("TVT Abbrevo") into Partie's vaginal wall on April 15, 2011. (ECF No. 6 at 5).

The TVT Abbrevo is made of synthetic monofilament polypropylene mesh and is generally used to treat pelvic organ prolapse or stress urinary incontinence ("SUI"). (*Id.;* ECF No. 11 at 2). In Partie's case, it was used to treat SUI. (*Id.*). Partie alleges that the polypropylene mesh caused her to develop chronic inflammation, also known as a "host defense response," which promotes tissue degradation and anatomic deformation. (ECF No. 11 at 3).

On February 9, 2017, Dr. Arthur Hepolsheimer diagnosed Partie with vaginal erosion for which she underwent corrective surgeries on March 17 and 24, 2017. (*Id.* at 2). During

these surgeries, it was determined that she suffered from grade 3 cystocele, grade 1 rectocele, and grade 1-2 vaginal vault prolapse. (ECF No. 6 at 5). Partie alleges that she suffered infection, pain, discharge, and mental anguish as a result of the above conditions. (ECF No. 11 at 2).

Partie also alleges that despite defendants' knowledge of the high rates of failure, injury, and complications associated with the TVT Abbrevo, they continued to market the device to the medical community while omitting and downplaying the risks and dangers of the product. (ECF No. 6 at 12–13).

Partie originally filed this action in state court on March 1, 2021. (ECF No. 1-2). Defendants removed the case to this court on July 20, 2021 (ECF No. 1), then moved to dismiss Partie's complaint on July 20, 2021 (ECF No. 4). Partie responded by filing her amended complaint on August 9, 2021, alleging claims of strict products liability—under theories of manufacturing defect, design defect, and failure to warn—, breach of express and implied warranty, fraud, and deceptive trade practices. (ECF No. 6).

Defendants now move to dismiss Partie's amended complaint. (ECF No. 9).

II. Legal Standard

A court may dismiss a complaint for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). A properly pled complaint must provide "[a] short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While Rule 8 does not require detailed factual allegations, it demands "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted).

"Factual allegations must be enough to rise above the speculative level." *Twombly*, 550 U.S. at 555. Thus, to survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (citation omitted).

First, the court must accept as true all well-pled factual allegations in the complaint; however, legal conclusions are not entitled to the assumption of truth. *Id.* at 678–79. Mere recitals of the elements of a cause of action, supported only by conclusory statements, do not suffice. *Id.* at 678.

Second, the court must consider whether the factual allegations in the complaint allege a plausible claim for relief. *Id.* at 679. A claim is facially plausible when the plaintiff's complaint alleges facts that allow the court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *Id.* at 678.

Where the complaint does not permit the court to infer more than the mere possibility of misconduct, the complaint has "alleged—but not shown—that the pleader is entitled to relief." *Id.* (internal quotation marks omitted). When the allegations in a complaint have not crossed the line from conceivable to plausible, plaintiff's claim must be dismissed. *Twombly*, 550 U.S. at 570.

The Ninth Circuit addressed post-*Iqbal* pleading standards in *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). The *Starr* court stated, in relevant part:

> First, to be entitled to the presumption of truth, allegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively. Second, the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.
>
> *Id.*

If the court grants a Rule 12(b)(6) motion to dismiss, it should grant leave to amend unless the deficiencies cannot be cured by amendment. *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992). Under Rule 15(a), the court should "freely" give leave to amend "when justice so requires," and absent "undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments . . . undue prejudice to the opposing party . . . futility of the amendment, etc." *Foman v. Davis*, 371 U.S. 178, 182 (1962). The court should grant leave to amend "even if no request to amend

the pleading was made." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks omitted).

III. Discussion

Partie's amended complaint enumerates several causes of action against defendants. (*See* ECF No. 6). The court first addresses Partie's strict products liability claims, then her breach of warranty, fraud, and deceptive trade practices claims.

A. Partie's manufacturing defect claim fails because she fails to allege that the TVT Abbrevo was defective when it left the manufacturer or that it suffered an unexpected and dangerous malfunction

Partie alleges that the TVT Abbrevo is defectively manufactured. (ECF No. 6 at 22). To successfully plead a strict products liability claim under a manufacturing defect theory, a plaintiff must show that 1) the product had a defect which rendered it unreasonably dangerous, 2) the defect existed at the time the product left the manufacturer, and 3) the defect caused the plaintiff's injury. *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992). However, evidence of an unexpected, dangerous malfunction permits an inference of a manufacturing defect. *Krause Inc. v. Little*, 34 P.3d 566, 571–72 (Nev. 2001). In such a situation, direct proof of the malfunction's cause is unnecessary; the circumstantial evidence of the malfunction can prove a manufacturing defect. *Id.* at 572.

Partie does not allege that the pelvic mesh products implanted in her body were defective at the time they left the manufacturer. (ECF No. 6 at 17). Rather, she asserts that they were "in the same or substantially similar condition *as they were safe when they left Defendants' possession,* and in the condition directed by and expected by defendants." (*Id.*) (emphasis added).

This allegation runs counter to prong two of the test articulated in *Fyssakis*. Clearly, Partie cannot plead a successful manufacturing defect claim on these grounds. Rather, she must rely on the "unexpected, dangerous malfunction" exception articulated in *Krause.*

To that end, Partie references a statement Dr. Hepolsheimer made six years after her initial implantation that her vaginal erosion was caused by her surgical mesh implant. (ECF No. 6 at 5). Although the court accepts as true Partie's allegation that Dr. Herpolsheimer

believes Partie's injuries were caused by the implant, this is not sufficiently plausible evidence of an unexpected, dangerous malfunction.[1]

Accordingly, Partie fails to state a claim of manufacturing defect.

B. Partie's design defect claim fails because she alleges nothing more than generic defects and conclusory statements that the TVT Abbrevo was defective

Nevada analyzes design defect claims under the consumer expectations test, which provides that "a product is defective when it 'fails to perform in the manner reasonably to be expected in light of its nature and intended function and was more dangerous than would be contemplated by the ordinary user.'" *Miller v. DePuy Synthes Sales, Inc.* No. 3:17-CV-00325-RCJ-CBC, 2019 WL 4016207, at *4 (D. Nev. Aug. 26, 2019), aff'd, 837 F. App'x 472 (9th Cir. 2020) (quoting *Ford Motor Co. v. Trejo*, 402 P.3d 649, 650 (Nev. 2017)). Additionally, the plaintiff must show that the design defect in the product was a substantial factor in causing her injury. *Asay v. Kolberg-Pioneer*, No. 2:08-CV-01242-LRH, 2010 WL 3239006, at *5 (D. Nev. Aug. 13, 2010).

A consumer's reasonable expectations are typically influenced by the warning which accompanies the product. *Miller*, 2019 WL 4016207, at *4. Therefore, warnings shield manufacturers from liability unless the defect could be avoided by a commercially feasible change in design. *Robinson v. G.G.C., Inc.*, 808 P.2d 522, 525 (Nev. 1991).

Here, Partie alleges that the injuries and conditions from which she currently suffers are "clearly" caused by design defects with the TVT Abbrevo. (ECF No. 6 at 24). She attempts to buttress this conclusory statement with a list of injuries suffered by *other* individuals implanted with Ethicon's devices that are allegedly caused by design defects. (ECF No. 6 at 23-24). However, even taken as true, these allegations do not plausibly show a design defect or causation.

Other than Dr. Herpolsheimer's statement, discussed *supra*, Partie pleads no facts to refute defendants' notion that her injuries were caused by her 2011 surgery and not the TVT

[1] Partie pleads that Nevada applies the consumer expectations test to manufacturing and design defects. (ECF No. 6 at 20–21). As discussed *infra*, that argument also fails.

Abbrevo. To successfully bring a design defect claim under the *Twombly/Iqbal* pleading standard, plaintiffs must allege more than a list of generic defects or conclusory statements that the product was defective. Therefore, Partie fails to state a claim for relief under the consumer expectations test.[2]

Accordingly, Partie fails to state a claim of design defect.

C. Partie successfully states a failure to warn claim at this dismissal stage

To successfully plead a failure to warn claim, a plaintiff must prove more than just that no warning was provided, but also that either the inadequacy or absence of a warning caused the plaintiff's injury. *Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004).

Here, Partie alleges that defendants failed to provide any reasonable warning or instruction to either her or her physician. (ECF No. 6 at 26). She further asserts that an adequate warning would have prompted her to consider different treatment. (*Id.*). At this dismissal stage, the court takes as true Partie's allegation that her doctor did not receive an adequate warning.[3] Defendant's arguments to the contrary are better left for a summary judgment determination on an adequate warning affirmative defense.

Accordingly, Partie's claim for failure to warn survives dismissal.

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[2] In her amended complaint, Partie also posits that a there was a "reasonable, feasible, and available" alternative design to the polypropylene used by Ethicon. This is a clear reference to the risk-utility test, which states that "a product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design." RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(B) (AM. LAW. INST. 1998). The Nevada Supreme Court has declined to adopt this test and continues to govern claims of design defect under the consumer expectations test. *Ford Motor Co.*, 402 P.3d at 651. The court is disinclined to depart from this precedent.

[3] Defendants argue that they did provide adequate warning to Partie's doctor, in the form of the instructions for use ("IFU"), attached as ECF 12-2. Defendants also attach the Declaration of Mr. Reynaldo Librojo (ECF No. 12-1) as evidence that the IFU accompanied the TVT Abbrevo during the time period when Partie was implanted with it. However, this does not prove that these instructions were in fact provided to Partie's doctor. The IFU is not incorporated by reference to Partie's complaint, and defendants fail to offer some other exception to the general rule that motions to dismiss are determined just on the allegations provided in the complaint.

D. Partie successfully states claims for breach of express and implied warranty because defendants arguably had pre-suit notice of the breach and Partie arguably brought her claims within the statute of limitations

To state a breach of warranty claim under Nevada law, a plaintiff must allege the existence of a warranty, that the defendant breached the warranty, and that the breach was the proximate cause of the plaintiff's injury. *Scovil v. Medtronic Inc.*, No. 2:14-CV-00213-APG, 2015 WL 880614, at *12 (D. Nev. Mar. 2, 2015) (quoting *Nevada Contract Servs., Inc. v. Squirrel Cos. Inc.*, 68 P.3d 896, 899 (Nev. 2003)). Where delivery of goods has been accepted, "[t]he buyer must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." NEV. REV. STAT. 104.2607(3)(a).

Partie argues that defendants breached the express warranty because (1) they expressly warranted that the device at issue was safe, effective, fit, and proper for its intended use, (2) she and her doctor chose the device based on their reasonable reliance of defendants' warranties and representations regarding its safety and fitness, and (3) the device implanted in Partie was unreasonably dangerous and defective. (ECF No. 6 at 27–28).

Defendants counter that these claims must be dismissed because (1) Partie did not provide defendants with pre-suit notice of any alleged breach of warranty and (2) the breach of warranty claims are barred by Nevada Revised Statute ("NRS") § 104.2725, which establishes a four-year statute of limitations for breach of warranty claims beginning when tender of delivery is made. (ECF No. 9 at 16).

The central issues here are whether (1) pre-suit notice of breach of warranty was provided to defendants, and (2) any of the representations made by defendants regarding the TVT Abbrevo created an express or implied warranty that extended to the device's future performance. First, Partie argues that NRS 104.2607(3)(a) does not require her to give pre-suit notice to the defendants. Rather, the defendant only need be on notice that the transaction is "troublesome and must be watched." (ECF No. 11 at 12). Partie avers that such notice is provided by (1) the original complaint, (2) an FDA public health notification, (3) an FDA white paper, (4) an FDA safety communication and joint committee opinion, and

(5) a body of scientific and medical literature reporting that the device in question is "causally associated with the injuries, conditions, and complications" experienced by Partie. (ECF No. 11 at 12–13).

These allegations of notice are sufficiently plausible to survive this dismissal stage. Accordingly, defendants' motion is denied as to Partie's claims for breach of warranty.

Second, the amended complaint does not mention the date on which Partie began to experience pain and suffering, nor does it establish a precise date when her vaginal erosion and other injuries occurred. What is known is that Partie underwent surgeries on March 17, 2017, and March 24, 2017, to treat exposure of mesh material to the bladder neck and to treat grade 3 cystocele, grade 1 rectocele, and grade 1-2 vaginal vault prolapse. At this point, Partie certainly should have known that a breach of warranty had taken place. Because she initially filed her claim in state court on March 1, 2021, it is sufficiently plausible that she brought these claims within the four-year statute of limitations.

Accordingly, Partie successfully states a claim for breach of express or implied warranty.

E. Partie's claims of fraud and deceptive trade practices fail because they are not pleaded with the requisite particularity of Federal Rule of Civil Procedure 9(b)

Federal Rule of Civil Procedure 9(b) requires a party bringing a fraud claim to "state with particularity the circumstances constituting fraud or mistake." When, as here, a fraud claim is based on misrepresentations, the plaintiff is required to "identify the who, what, when, where, and how of the misconduct charged," as well as what is false or misleading about the purportedly fraudulent statement, and why it is false." *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010).

Here, Partie's complaint is deficient. It merely sketches vague statements of how defendants continued to market the pelvic mesh products to the medical community despite that the devices failed to perform as intended, required re-operations, and often caused severe

and irreversible injury. (ECF No. 6 at 30–31). This is far from the particularity required by Rule 9(b).[4]

Partie's deceptive trade practices claim suffers from similar issues as her fraud claim. Deceptive trade practices claims must also be plead with Rule 9(b) particularity. *Sommers v. Cuddy*, No. 2:08-CV-78-RCJ-RJJ, 2012 WL 359339, at *4 (D. Nev. Feb. 2, 2012); *see also Weinstein v. Mortg. Cap. Assoc., Inc.*, 2011 WL 90085 at *4 (D. Nev. 2011).

The Nevada Revised Statutes provide several definitions of "deceptive trade practices." NEV. REV. STAT. § 598.0915. Relevant here are paragraphs 7—"represents that goods or services for sale or lease are of a particular standard, quality, or grade, or that such goods are of a particular style or model, if he or she knows or should know that they are of another standard, quality, grade, style or model"—and 15—"knowingly makes any other false representation in a transaction."

Here, Partie does not establish the "knowing" aspect of the statute in her amended complaint. Instead, she makes a conclusory statement that the defendants "intentionally, recklessly, and/or negligently concealed, suppressed, omitted, or misrepresented the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device when, in fact, Defendants knew that the Pelvic Mesh Products were not safe for their intended purposes . . . ." (ECF No. 6 at 34). This is exactly the type of speculative and conclusory statement that fails to state a claim for relief under the *Twombly/Iqbal* pleading standard.

Because Partie pleads neither fraud nor deceptive trade practices with sufficient particularity, those claims are dismissed.

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[4] In her response to Ethicon's motion to dismiss, Partie attempts to convince the court that she identified the who—defendants—, what—representations that their products were safe and effective—, when—following 2008 and 2011 studies—, where—marketing materials—and why—profit motive. (ECF No. 11 at 20). However, this type of post-hoc retrofitting does not correct the deficiencies in the amended complaint.

IV. Conclusion

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that defendants' motion to dismiss (ECF No. 9) be, and the same hereby is, GRANTED in part and DENIED in part. Defendants' motion is denied as to Partie's failure to warn, breach of express warranty, and breach of implied warranty claims, and granted as to all other claims. Partie's claims for design defect manufacturing defect, fraud, and deceptive trade practices are DISMISSED, without prejudice.

DATED July 1, 2022.

James C. Mahan

UNITED STATES DISTRICT JUDGE